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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,634	04/05/2007	Mitchell C. Sanders	ETH5160USPCT [14972]	4673
25570 7590 08/20/2009 ROBERTS MLOTKOWSKI SAFRAN & COLE, P.C. Intellectual Property Department P.O. Box 10064 MCLEAN, VA 22102-8064			EXAMINER SHEN, BIN	
			ART UNIT 1657	PAPER NUMBER
			NOTIFICATION DATE 08/20/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/576,634		SANDERS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	BIN SHEN		1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 16-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                 |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application       |
| Paper No(s)/Mail Date <u>4/16/2007, 7/11/2007</u> .                                    | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> . |

### **DETAILED ACTION**

The IDS received 4/16/2007, 7/11/2007, the preliminary amendment received 4/21/2006 have been entered.

#### ***Election***

Applicant's election with traverse of Group I, claims 1-15, election of species of SEQ ID NO:23, in the reply filed on 4/7/2009, and election of species of a vinyl sulfone dye, a polymer support, a body fluid sample, a membrane collector, a lysine enzyme in the reply filed on 6/12/2009 is acknowledged. The traversal is on the ground(s) that the cited reference, WO 03/063693 does not teach a visible color change. This is not found persuasive because the cited reference teaches a visible color change on page 10, line 3, and page 16, line 24, also see the 102 (b) rejections below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-26 are nonelected because they drawn to nonelected claims and thus are withdrawn from further consideration.

Only claims 1-15 are presented for examination on the merits.

Benefit of priority is to 11/3/2003.

#### ***Drawings***

The drawings are objected to because the images are not recognizable in Figures 5, 6, 7, 8, 9, 16, 17. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The specification is objected to for inappropriate notation of an internet address. The specification contains an embedded hyperlink at page 11, line 27, and page 27, line 21 and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Removal of the "http://" is sufficient to comply.

All references to sequences in specification must include SEQ ID NOs, sequence identifier is missing for the amino acid sequence at the end of page 47.

The specification is objected to for the legend of Figure 8, on page 6, it refers to "Figure 22A", where is "Figure 22A"?

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase "modification" for the following reasons. It is unclear what "modification" defines. What kind of modification is the method detecting? It appears only enzymatic activity such as proteolytic activity is described in the

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application. Claim 1 is rendered vague and indefinite by the phrase “a sample”. It is unclear what activity in the sample the method is detecting.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7-12, 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Sanders et al. (WO03/063693).

Sanders et al. teach a method of detection of the presence of bacteria by enzymatic (protease and lipase in Examples 9 and 13, and autolysin in Example 10) cleavage of labeled substrate that changes colors (see for example, page 38, Example 9, page 40, Example 10, and page 42 Example 13).

Therefore, Sanders teaches a method for detecting the modification of a peptide substrate by exposing an unmodified dye (for example, two different dyes: edans (5-((2-aminoethyl)amino)naphthalene-1-sulfonic acid and dabcy1 994-(4-(dimethylamino)phenyl)azo)benzoic acid see page 43, , **Claims 5 & 7**) labeled peptides (peptide substrates PAPA1/PALA1/PAGA1, page 42, example 13, and peptide substrate PAPA1 has the same sequence as SEQ ID NO:2 of the instant application, **Claim 4**) substrate on a solid support: wound dressing ( page 4 lines 1-3, such as a wound dressing-page 26, 4<sup>th</sup> full paragraph, **Claims 1, 2, 8, 10, 11**) to a wound sample (such as body fluid, **Claim 12**, page 2, 1st paragraph), wherein the visible color change (by the cleavage of the dye, **Claims 3, 9**, for visible color change see page 10, line 3, and page 16, line 24) indicates the presence of a wound specific bacteria enzyme (see Example 9 for lipase and Example 10 for autolysin and Example 13 for protease and lipase, and also see page 11, 1<sup>st</sup> full paragraph, **Claim 15**).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Asai (1984).

Asai teaches a method for detecting substrate modification by thrombin (enzyme) hydrolysis of a dye labeled peptide substrate (PS-915) that turns blue (abstract, line 6).

Therefore, Asai teaches a method (**Claims 1**) for detecting thrombin (enzyme) hydrolysis of a covalently linked dye-peptide substrate (PS-915), (**Claims 1, 2, 3**) wherein the dye is a reactive dye (CHA: 3-carboxy-4-hydroxyaniline, abstract, line 5) that turns blue (page 165, lines 6-7, **Claim 5**) and the sample tested for the enzyme is body fluid plasma (page 165, line 1, **Claim 12**).

Claims 1-3, 5, 8, 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kulisek (1989).

Kulisek teaches a chromogenic assay for the detection of plasmin immobilization on nitrocellulose using the plasmin specific dye labeled tripeptide substrate, H-D-valyl-leucyl-lysine-p-nitroaniline, wherein the releasing of para-nitroaniline from the peptide substrate forms an intense red color in the presence of diazonium salt (abstract; lines 4-10).

Therefore, Kulisek teaches a method (**Claims 1**) for detecting plasmin (enzyme) cleavage of a covalently linked dye-peptide substrate (H-D-valyl-leucyl-lysine-p-nitroaniline) of plasmin, (**Claims 1, 2, 3**) wherein the dye is a reactive dye (para-nitroaniline) that turns red (abstract, line 10, **Claim 5**), the peptide substrate is coupled to a solid support (**Claim 8**) agarose (read as resin, **Claim 11**, page 80, left column, 3<sup>rd</sup> full paragraph), and the sample tested is a nitrocellulose membrane impregnated with bacterial colonies (page 80, right column, 1<sup>st</sup> full paragraph, lines 2-4, and the nitrocellulose membrane is also read as a collector because the color changes to red in the developed membranes, **Claim 12 -14**, page 80, end of left column to the top of right column, lines 1-5), the method identifies streptokinase (read as a metabolic enzyme) from streptococcal strains (page 83, right column, 1st full paragraph, **Claim 15**).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 & 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kulisek and Graham (1995).

Kulisek teaches what is above.

Kulisek does not teach the visible color change is a loss of color.

Graham teaches a chromogenic assay for the detection of a trypsin inhibitor with a dye labeled trypsin substrate that reduce/eliminate yellow color development (read as loss of color, page 165, 5<sup>th</sup> paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kulisek by using loss of color (**Claim 6**) for the detection of the substrate modification because Graham teaches the loss of color can indicate the presence of an trypsin inhibitor, thus a color substrate can be used to detect the presence of an enzyme by its color loss. One would have been motivated to make the modification because Graham et al. specifically described a loss of color for detection of enzyme inhibitor, and would reasonably have expected success in view of Kulisek and Graham's teachings because they both use chromogenic assay thus if a colored substrate is chosen for the assay, the loss of color would indicate the presence of enzyme/inhibitor.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8, 11, 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16, 18, 20, 35, 37, 39, 53, 57 of copending Application No. 10502882. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same method steps are claimed where the instant application detects color change specifically (narrower). Therefore, the claims of the instant application are rendered obvious in view of those (broader claims) of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If



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Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

*B Shen*

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/Karen Cochrane Carlson/  
Primary Examiner, Art Unit 1656